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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/228,020	01/11/1999	JEFFREY M. ISNER	46963-DIV	7379

7590

04/17/2002

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/17/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N 09/218020	Applicant(s) J SWEET	
	Examiner GAMBEL	Art Unit 1644	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on \_\_\_\_.

2a) ☐ This action is FINAL.      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) \_\_\_\_ is/are pending in the application. 1-64

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration. 1-19, 21, 22

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☒ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement. 20, 23-64

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	6) <input type="checkbox"/> Other: ____

### DETAILED ACTION

1. Applicant's election of the species VEGF in Paper No. 16, filed 1/28/02, is acknowledged.

Upon a review of the elected claims 20 and 23-64, the following species elections have been set forth herein. The examiner apologizes for any inconvenience in this matter.

Claims 1-19, 21 and 22 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions

2. The examiner notes the following.

Applicant is invited to amend the claims to recite endothelial progenitor cells that are CD34<sup>+</sup>, flk-1<sup>+</sup>, tie-2<sup>+</sup>, as currently claimed in priority application USSN 08/744,882, now U.S. Patent No. 6,121,246. It appears that endothelial progenitor cells that are CD34<sup>+</sup>, flk-1<sup>+</sup>, tie-2 are free of the prior art.

Keller et al. (U.S. Patent No. 5,874,301) is made of record and is considered pertinent to applicant's disclosure.

Claim 20 should be amended to recite "endothelial cell (EC)" so that "EC" is clearly defined in the independent claim.

Claim 34 should recite "CD34" as the proper nomenclature rather than "CD-34".

It is noted that claims 49-50 and 64 appear to be directed towards methods or encompass method limitations and not products, as recited in the claimed preamble. Therefore, their limitations add no patentable weight to the product claims.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the endothelial cell progenitors are:

- A) not transfected nor coupled with an agent recited in claim 48,
- B) transfected with a cytotoxic agent,
- C) transfected with a cytokine,
- D) transfected with a co-stimulatory molecule to stimulate an immune reaction,
- E) transfected with an anti-tumor drug,
- F) transfected with an angiogenesis inhibiting agent.
- G) coupled with a cytotoxic agent,
- H) coupled with a cytokine,
- I) coupled with a co-stimulatory molecule to stimulate an immune reaction,
- J) coupled with an anti-tumor drug, or
- K) coupled with an angiogenesis inhibiting agent.

These species are distinct because their structures and modes of action are different.

In addition, applicant should elect an ultimate species as it reads on (B) - (K), depending on which species of (B) - (K) is elected. For example, see the species recited in claims 52-63

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20, 39 and 40 are generic, for example.

4. If the heterologous nucleic acid sequences selected from the species from claims 52-56 are not included in the Groups 5 (B)- (F) above, then this application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the endothelial cell progenitors include heterologous nucleic acid sequences selected from the species from claims 52-56.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20, 39 and 51 are generic, for example.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

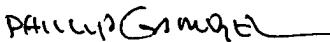
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
April 16, 2002